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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,468	07/10/2000	Morten Sloth Weidner	04590461P	9245

2292 7590 02/19/2004

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,468	WEIDNER, MORTEN SLOTH	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,17,18 and 26-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 17-18, and 26-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments filed received on November 12, 2003 is acknowledged. Claims 1-9, 17-18, and 26-38 are pending in this application.

Claim Rejections - 35 USC § 112

Rejection of claims 4, 27, 29, and 31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments made and arguments clarifying the limitations.

Claim Rejections - 35 USC § 102

Rejection of claims 17-18 under 35 U.S.C. 102(b) as being anticipated by Zabotto et al (4,661,343) is withdrawn in view of applicant's arguments and the Rule 132 Declaration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rejection of claims 1-5, 7-9, 17-18, and 26-38 under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393) is maintained.

Laur et al teach a pharmaceutical composition with shea butter fractions containing triterpene alcohols and sterols (col. 111, lines 40-51). Laur et al teach the composition in a topical emulsion form containing 1-60% unsaponifiable material (Note examples). Laur et al also teach that the mixture may be incorporated in an amount of 0.5-99%. See column 5, lines 45. The unsaponifiable material contains sterols, karitenes, and triterpene alcohol. See column 11-12. The amount of lupeol, amyrin, sterols, and butyrospermol in the triterpene fraction are inherent (also based upon applicant's calculations on page 4 of arguments of paper no. 15). Laur et al disclose the unsaponifiable material from shea butter and other plants, have valuable properties for the fields of cosmetology, pharmacy, or medicine (col. 2, lines 29-33). Lastly, Laur et al teach the composition has anti-inflammatory activity. See column 5, lines 24-25.

Laur et al does not exemplify instant amount of lupeol or butyrospermol of the total composition.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance of Laur et al and manipulate the amount of lupeol or butyrospermol desired in the composition. One would be motivated to do so since Laur teaches approximately 4.4% of butyrospermol and 3.9% of lupeol in one embodiment based on 30% unsaponifiable material. However, Laur et al does teach utilization of 99% of the unsaponifiable material. Thus, based on the amount of unsaponifiable

material utilized the amount of the individual components will change and the prior art's teachings clearly extend into the instant range of lupeol or butyrospermol in the total composition. Further the desired concentration of each individual component depends on the nature and process of extraction and Laur et al provides the general guidance of shea butter extraction. The mere optimization of ranges of prior art conditions through routine experimentation does not support patentability of subject matter encompassed by the prior art unless there is evidence of unexpected results.

Lastly, is deemed obvious to one of ordinary skill in the art at the time the invention was made to provide the karite composition in a topical or systemic dosage form since dosage forms are known to a skilled practitioner in the art. The dosage form depends on the area and symptoms to be treated, thus one would be motivated to use the appropriate dosage form according to the condition to be treated.

Response to Arguments

Applicant argues that Laur et al does not disclose all the limitations of the instant invention. Applicant acknowledges Laur et al teach unsaponifiable fraction material, however the reference does not teach the instant amount of lupeol, amyrin, and butyrospermol are responsible for the desirable pharmaceutical properties. Applicant argues unexpected results of increased anti-inflammatory effect in the specification.

Applicant's arguments have been fully considered but they are not persuasive. The examiner notes that Laur teaches that 0.5-99% of the composition contains unsaponifiable and 18-50% is unsaponifiable compounds. However, Laur et al still

reads on the instant invention based on the calculations the applicant made in the Response to Arguments dated May 23, 2003:

> "Content of individual triterpenes in a composition according to Laur et al:
>
> Butyrospermol: 4.4 %.
>
> alpha-Amyrin and/or beta-Amyrin: 10.6%.
>
> Lupeol: 3.9 %.
>
> Thus, a composition of Laur that comprises 60% of an extract comprising 50% of unsaponifiable material would inherently contain about 21% of a triterpenic fraction. And, consequently, such compositions would inherently contain about 4.4% of butyrospermol. 3.9 % of Lupeol and 10.6 % of a-Amyrin and o-Amyrin"

This calculation was based on the erroneous assumption that Laur taught a maximum amount of 60% of unsaponifiable material with a maximum of 50% of unsaponifiable compounds. However, the examiner has pointed out that Laur et al teach a range of 0.5-99% with 50% unsaponifiable compounds. The art does not have to exemplify a range in a 103 rejection, it merely has to suggest the range. Thus, it is clear that if a skilled artisan utilized the maximum range taught by Laur et al, Laur's range would clearly overlap the instant range.

Even if one were to argue solely on the basis of the calculations presented by applicant of 4.4% Butyrospermol, 10.6% alpha-Amyrin and/or beta-Amyrin, 3.9% Lupeol, and 21% triterpene fraction, the ranges are still obvious. The claim requires at least 5% of the fraction, which the applicant has established Laur et al teaches. The

claim requires at least 2% of butyrospermol, amyrin, and lupeol, which applicant has established Laur et al teaches. The only percentage missing is 5-90% of lupeol *or* butyrospermol in the composition. It is the examiner's position that 4.4% of butyspermol and 5% are a close and a comparable range unless applicant provides unexpected results.

The applicant argues that the instant fraction is enriched via a certain "unique" process. However, a careful examination of the specification demonstrates that Laur et al and applicant utilize the similar extraction procedure. On page 15 of instant specification, applicant states that acetone is the preferred solvent and that certain solvents allow for one to select or reduce the amount of certain constituents in Butyspermol. Further, applicant states that the instant invention provides an enriched fraction. The examiner points out that Laur et al not only utilize an acetone solvent in the examples but also emphasize enriched fractions on column 12, lines 40-45. Therefore, clearly Laur et al teaches the criticality of enriching a composition with the unsaponifiable compounds and thus provides motivation to increase the amount of the said unsaponifiable matter.

In regards to the argument that Laur et al does not recognize that the individual components reduce inflammation. The examiner points out that in a product claim the individual role of each component need not be defined by the prior art, the art merely has to contain the said components in the instant amount or in an obvious range. If the prior art contains the instant component, it will implicitly function is such a manner without explicitly stating so. A newly discovered function of a component in a prior art

product does not extend patentability since the prior art inherently possesses the function. See In re Best. Furthermore, the examiner points to column 7, lines 1-8 wherein Laur recognizes the anti-inflammation properties of the components and the need to further investigate this.

Lastly, in regards to the unexpected results, the examiner points out that in order to provide an accurate demonstration of unexpectedness, the applicant must provide a comparison with the closest prior art. This has not been provided and therefore, Laur et al cannot be overcome with this argument.

Therefore, the rejection is maintained.

Rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393) in view of SU 1181171 is maintained.

As set forth, Laur et al a composition with shea butter fractions containing triterpene alcohols and sterols, which has anti-inflammatory activity (col. 111, lines 40-51).

Laur et al do not teach Calendula officinalis in the composition.

SU 1181171 teaches the anti-inflammatory properties of the marigold plant and its extract (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add marigold extract in Laur et al's composition. One would be motivated to do so with a reasonable expectation of at least an additive if not a synergistic effect in the composition since Laur teaches the anti-inflammatory activity of the composition and SU 1181171 teaches the anti-inflammatory properties of marigold.

Response to Arguments

Applicant arguments do not specifically pertain to instant rejection and only argue Laur et al. Applicants arguments have been addressed above and therefore the rejection has been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG
February 13, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER